Atty. Dkt. No. 029318-0972

IN THE PATED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Jain et al.

Title:

RAPIDLY DISINTEGRATING SOLID ORAL DOSAGE FORM

Appl. No.:

10/667,470

Filing Date:

September 23, 2003

Examiner:

Unassigned

Art Unit:

1615

Confirmation

9048

Number:

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR §1.56</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

The documents listed on the PTO/SB/08 were cited by the Examiner in corresponding Patent Application Nos. 10/712,259 and 10/323,736.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Jnder the Pap number.	erwork Reduction Act of 1995, no par	sons are require	d to respond to a collection of inf	formation unless it contains a valid OMB control	
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	STATEMENT BY				Filing Date	September 23, 2003	
					First Named Inventor	Jain et al.	
					Group Art Unit	1615	
	(use as many sheets	s as ne	ecessary)		Examiner Name	Unassigned	
Sheet	1	of	1		Attorney Docket Number	029318-0972	

				U.S. PATENT DOCUMENTS		
Examiner Initials*	Cite No.1	U.S. Patent Document			Date of Publication of	Pages, Columns, Lines Where Relevant
		Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
	A1	5,356,467		Oshlack et al.	10/18/1994	
	A2	4,540,602		Motoyama et al.	09/10/1985	
	A3	4,814,175		Tack et al.	03/21/1989	
	A4	4,562,069		Hegasy et al.	12/31/1985	

Examiner Initials*	Cite No. ¹	Foreign Patent Document Office ³ Number ⁴ Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ'
	A5	GB 2 166 651 A	Geoghegan	05/14/1986		

		NON PATENT LITERATURE DOCUMENTS	_
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A6	Guidance for Industry, Levothyroxine Sodium Tablets-In Vivo Pharmacokinetic and Bioavailability Studies and in Vitro Dissolution Testing, U.S. Department of Health and Human Services, Food and Drug Administration, Dec. 2000, pgs. 1-8.	

Examiner Signature	Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.